MAY 13 1999

K984486

Attachment I
510(K) Summary
American Dental Technologies PulseMaster Dental Laser Systems

This 510(K) Summary of safety and effectiveness for the American Dental Technologies PulseMaster Dental Laser systems is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	American Dental Technologies, Inc.
Address:	18860 West Ten Mile Road Southfield, MI 48075-2657
Contact Person:	John Sulewski
Telephone:	(248) 395-3900 – Phone (248) 395-3801 – Fax
Preparation Date:	12-16-98
Device Trade Name:	PulseMaster Dental Laser Systems
Common Name:	Nd:YAG Pulsed Laser
Classification Name:	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878-48
Legally Marketed Predicate Device:	The Centauri Dental Laser manufactured by Premier Laser Systems, #3 Morgan Street, Irvine, CA , previously cleared for market under 510(k) number K932683.
Description of the American Dental Technologies PulseMaster Dental Laser Systems	The American Dental Technologies PulseMaster Dental Laser Systems are Nd:YAG lasers producing laser emission at 1064 nm. The lasers consist of two interconnected sections: The cabinet which houses the laser head, the power supply, the cooling system and the microprocessor with control panel; and the fiber optic delivery system.
Intended use of the American Dental Technologies PulseMaster Dental Laser Systems	The American Dental Technologies, Inc. PulseMaster Dental Laser Systems are indicated for use for selective ablation of first degree enamel caries.
Nonclinical Performance Data:	Bench test data were collected under controlled scientific conditions to establish the substantial equivalence of the PulseMaster Dental Laser Systems to a pulsed Er:YAG Dental Laser. We measured the temporal pulse structures and effects on enamel caries and found the two lasers to be equivalent.

Clinical Performance Data:	An extracted tooth study was conducted to evaluate the histological effects of the laser treatment. The histology indicated that the device is safe for the intended use. Clinical data from a multi-center, blinded, randomized study comparing the PulseMaster to the highspeed handpiece established the safety and effectiveness of the PulseMaster Dental Laser Systems for the Intended use.
Conclusion:	The American Dental Technologies PulseMaster Dental Laser Systems are substantially equivalent to another existing surgical laser system in commercial distribution for selective ablation of enamel caries and to commercially available High Speed Dental Handpieces.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1999

Mr. John G. Sulewski
Product Manager
American Dental Technologies, Inc.
18860 West Ten Mile Road
Southfield, Michigan 48075-2657

Re: K984486
Trade Name: PulseMaster Dental Laser Systems
Regulatory Class: II
Product Code: GEX
Dated: March 15, 1999
Received: March 16, 1999

Dear Mr. Sulewski:

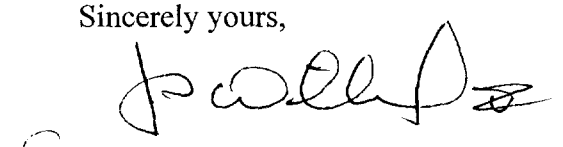
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K984486 New Submission

Device Name: PulseMaster Dental Laser Systems

Indications for Use:

The American Dental Technologies, Inc. PulseMaster Dental Laser Systems are indicated for use for selective ablation of enamel (first degree) dental caries.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices K984486
510(k) Number

Prescription Use X
(per 21 CFR 801.109)

OR

Over-the-Counter Use____